



ATTORNEYS AT LAW-

COMMISSIONER FOR PATENTS ALEXANDRIA, VIRGINIA 22313

RE: Application Serial No.: 09/892,577

Applicants: Shigefumi SAKAI, et al.

Filing Date: June 28, 2001

For: SKIN COSMETIC COMPOSITION

Group Art Unit: 1617 Examiner: Yu, G.C.

SIR:

Attached hereto for filing are the following papers:

Letter to PTO

Declaration Under 37 C.F.R. §1.132 (executed)

Our check in the amount of is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,

MAIER & NEUSTADT, P.C.

Norman F. Oblon

J. Derek Mason, Ph.D.

Registration No. 35,270

Customer Number

22850

(703) 413-3000 (phone) (703) 413-2220 (fax)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

Shigefumi SAKAI, et al.

SERIAL NO: 09/892,577

GROUP: 1617

FILED:

June 28, 2001

EXAMINER: Yu, G.C.

FOR:

SKIN COSMETIC COMPOSITION

LETTER

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith, for the Examiner's consideration, is a better resolution copy of the executed Declaration Under 37 C.F.R. §1.132 as discussed in the previous Amendment and filed on April 15, 2008.

Respectfully Submitted,

OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C.

Norman F. Oblon

J. Derek Mason, Ph.D. Registration No. 35,270

Customer Number

22850

Tel. (703) 413-3000 Fax. (703) 413-2220 (OSMMN 03/06) ocket No.:

210354US0

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

E APPLICATION OF:

GROUP: 1617.

Shigefumi SAKAI, et al.

SERIAL NO: 09/892,577

EXAMINER: YU, GINA C

FILED:

MAY 0 7 2008

June 28, 2001

FOR:

SKIN COSMETIC COMPOSITION

DECLARATION UNDER 37 C.F.R. § 1.132

COMMISSIONER FOR PATENTS ALEXANDRIA, VIRGINIA 22313

Sir:

Now comes Hideaki Kubo who deposes and states that:

- 1. I am a graduate of University of Osaka Prefecture and received my degree of Master of Chemical Engineering in the year 1987.
- 2. I have been employed by Kao Corporation for 21 years as a researcher in the field of chemical process development.
- 3. The following information is provided to show the significant differences between the present invention, which requires a CV of 5 or less for the hydrogel particles in the composition, compared to the CV obtained based upon information found in Delrieu.

The coefficient of variance (CV) is a normalized measure of dispersion of a probability distribution. It is defined as the ratio of the standard deviation s to the mean μ , as follows:

$$c_v = s/\mu$$

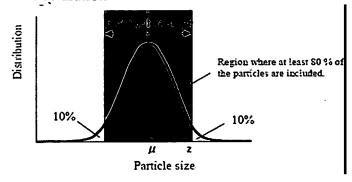
The CV is often reported as a percentage (%) by multiplying by 100. The use of the CV permits the comparison between data sets having different units or highly different means. Thus, a CV of 5 or less as required by the present invention means that the standard deviation must be 5% or less of the value of the mean particle size.

The standard deviation s of a given point Z can be calculated using a standard normal distribution chart.

For example, to calculate s of point Z, one determines the relative area of the entire curve up to the point Z, then locate the value on the chart that is closest to that relative area. Thus if the area up to point Z is 0.9 of the entire area, one locates the value closest to 0.9 (without exceeding 0.9), which is 0.8997. The result is Z is at 1.28s.

Turning to Delrieu, Delrieu states that their particles are preferred to have at least 80% of the particles, more preferably at least 90%, lie within a desired average particle size bracket extending ±30% on either side of the average particle size, as shown in the figure below (see column 5, lines 53-59 of Delrieu):

Application Number 09/892,577 Rule 1.132 Declaration



Thus, for the case where 80% of the particles are included within plus or minus 30% of the average particle size as required by Delrieu, the area from the far left of the curve to point Z is 90%. Thus, 1.28 s can be obtained as s of point Z based on the above chart. This gives:

$$1.28 \text{ s} = 0.3 \,\mu$$

Thus, $s = (0.3/1.28) \mu$, giving $s/\mu = 0.3/1.28 = 0.234$, or a CV of 23.4.

Similarly, for the case where 90% of the particles are within plus or minus 30% of the average particle size, applying the same calculations, one obtains 0.3/1.64 = 0.183, or a CV value of 18.3.

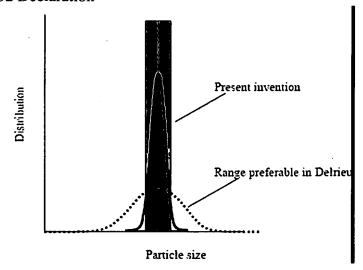
However, the present invention requires that the CV must be 5 or less for the hydrogel particles. This provides a highly uniform distribution. In particular, a CV of 5 gives $0.05 = s/\mu$. Thus, $s = 0.05 \mu$, or $2 s = 0.1 \mu$. Using the standard normal distribution chart:

$$\begin{aligned} \mathbf{Pr} \Big[\ \mathbf{y} \leq \mathbf{z} \ \Big] &= \int_{-\infty}^{\mathbf{z}} (\mathbf{v}) d\mathbf{y} & f(\mathbf{v}) = \frac{1}{\sqrt{2\pi}} e^{-\frac{\mathbf{z}}{2}} \\ &= \frac{1}{\sqrt{2\pi}} e^{-\frac{\mathbf{z}}{2}} \\ &$$

one obtains the following:

$$*1:1-(1-0.8413) \times 2=0.68$$
 $*2:1-(1-0.9772) \times 2=0.95$

Thus, for the present invention, at \pm 5% of the μ (mean particle diameter), there are 68% of the particles and at \pm 10% of the μ , there are 95% of the particles present. This is shown in the graph below, with a comparison to the range in Delrieu:



The resulting distribution of particles in the present invention is therefore much more highly compact than suggested or achievable by Delrieu. In fact, there is nothing with Delrieu or the other cited references to suggest how to obtain such a tight particle size distribution as required in the present invention.

- 4. The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.
 - 5. Further deponent saith not.

(OSMMN 05/06)

	Hideaki Kubo
	Signature
Customer Number 22850	Apr. 10, 2008
Tel. (703) 413-3000 Fax. (703) 413-2220	Date